Team Biologics Program Effectiveness; Public Meeting

Clarification of Discussion Topics

1. Assessing Industry Compliance with Applicable Laws and Regulations:

   a. Discuss how industry compliance can be measured and what tools should be used to evaluate the information.

   b. What criteria should be used in assessing the effectiveness of Team Biologics in achieving industry compliance?

2. Determining the Consistency of Our Inspection and Compliance Activities:

   a. What criteria should be considered in assessing the consistency of the Team Biologics' inspectional approach? You may include factors that relate to scope and depth of systems/products covered, scientific and regulatory knowledge, and skills of inspectional personnel, length and frequency of inspections, etc.

   b. Discuss your views on and/or experience with post-inspection outcomes based on Team Biologics inspections. Elaborate on the best way to determine if these outcomes (such as post-inspectional correspondence, administrative and legal actions, regulatory meetings, teleconferences, etc.) are consistently and fairly applied throughout the biologics industry.

3. Determining the Effects of Our Inspection and Compliance Activities on Product Quality:

   Define product quality. Discuss the approaches you feel would be useful in assessing the impact of inspections on overall product quality. Consider the scope of deviations from the cGMPs

that would trigger an assessment of product quality.

4. Assessing the Impact of Our Approach on Public Health:

What criteria should be considered when assessing Team Biologics' impact on product safety and availability?